QIAGEN GmbH
QIAGEN Strasse 1
40724 Hilden
Germany

December 2022

Urgent Field Safety Corrective Action

NeuMoDx™ Cartridge (REF 100100) LOTs 115424, 115425, 115426, 115427, 115429, 115431

Attention: Lab Director/Manager, Medical Director, Risk Manager, Safety Officer

Affected Product

Product	GTIN#	REF Number	Lot Numbers
NeuMoDx Cartridge	10814278020274	100100	115424, 115425, 115426, 115427, 115429, 115431

Description of the Issue

QIAGEN has become aware of the potential for false positive results to occur when the above lot of cartridges are used in conjunction with either of the following assays:

- NeuMoDx SARS CoV-2 Test Strip (REF 300800)
- NeuMoDx Flu A-B/RSV/SARS-CoV-2 Vantage Test Strip (REF 300900)
- NeuMoDx Laboratory Developed Tests (LDTs) for SARS-CoV-2 RNA detection

Note: Results for targets other than SARS-CoV-2 are not impacted by this Field Safety Corrective Action.

Potential Risks Associated with the Issue

False-positive results for SARS-CoV-2 could lead to incorrect management of symptomatic patients, including unnecessary isolation or quarantine, misallocation of resources, delayed diagnosis and treatment for other infections or health conditions, or unnecessary antiviral treatment. False-positive results for SARS-CoV-2 could also lead to cohorting of infected and non-infected patients together, which could result to spread of infection and subsequent increase in morbidity and mortality.

Actions Required by Customers

1. **IMMEDIATELY discontinue** use of the product and discard remaining inventory in accordance with your national and local safety and environmental regulations. Please contact QIAGEN Technical Service for a free-of-charge replacement of scrapped inventory.
2. Share this Field Safety Corrective Action with all users of the NeuMoDx Cartridges in your facility to ensure they are aware of this notice.
3. If you have already used NeuMoDx Cartridges from any of these lots in combination with the NeuMoDx SARS-CoV-2 Assay, the NeuMoDx Flu-A-B/RSV/SARS-CoV-2 Assay and NeuMoDx Laboratory Developed Tests (LDTs) for SARS-CoV-2 RNA detection please review all SARS-CoV-2 positive results to exclude erroneous diagnosis and treatment, except in those cases where alternative confirmation was obtained.

   Note: results for targets other than SARS-CoV-2 are not impacted by this Urgent Field Safety Corrective Action.
4. Complete the attached response form and return to Quality.Communications@qiagen.com to confirm receipt of this notification.

We sincerely apologize for any inconvenience this may have caused, and thank you in advance for your patience and cooperation.

If you have any questions regarding this notice, please contact **QIAGEN Technical Services.** Your local contact can be found at the following site: (https://www.qiagen.com/about-us/contact/global-contacts/subsidiaries/).

Sincerely,

Your QIAGEN Team

ACKNOWLEDGMENT FORM

Urgent Field Safety Corrective Action

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Please sign and date below to indicate that you have received and understood this correction notice and have **discontinued use of the product**. Your signature indicates that you have shared the information appropriately within your organization.

Note: this document may be shared with regulatory and administrative authorities as required by mandatory legislation. Please print in block letters.

QIAGEN Account Number (if known):

Company Name:

Your Name and Title (Printed):

Email address:

Telephone Number:

Number of Kits Discarded at Site

Signature (e-signature is accepted)

Date:

Please email this return response to **Quality.Communications@qiagen.com** or contact your local Technical Service Department to the attention of "QIAGEN Technical Service." Your local contact can be found at the following site: (https://www.qiagen.com/about-us/contact/global-contacts/subsidiaries/).